

AUG 21 2003

K032282

p. 1/2

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

**The Hydrocel Trabecular Metal Reconstructive System**

**Submitter Name:** Implex Corp.  
**And Address:** 80 Commerce Drive  
Allendale, New Jersey 07401-1600  
**Contact Person:** Marci Halevi  
**Phone Number:** (201) 818 - 1800, X 507  
**Fax Number:** (973) 829 - 0825  
**Date Prepared:** July 22, 2003  
**Device Trade Name:** The Hydrocel Trabecular Metal Reconstructive System  
**Device Common Name:** Surgical Mesh  
**Classification Number and Name:** 21 CFR § 878.3300  
Surgical Mesh

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**Substantial Equivalence:** The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without premarket approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

**Device Description:** The *Hydrocel Trabecular Metal Reconstruction System* is manufactured wholly of Hydrocel porous tantalum. Hydrocel porous tantalum is 80% porous with fully interconnecting pores that are about 0.5mm in diameter. This line extension adds components with a variety of cross-sections and heights to the *Hydrocel Trabecular Metal Reconstruction System*.

MATERIALS: Tantalum (Hydrocel porous tantalum)

**Indications for Use:** The Hydrocel Trabecular Metal Reconstruction System is indicated for use in reinforcing weak and/or deficient bony tissues in orthopaedic surgical procedures such as pelvic reconstruction, acetabular reconstruction, cement restriction, and in long bone procedures such as femoral and humeral reconstruction. When used in long bone procedures, ancillary fixation, such as plates and screws, must be used. The Hydrocel Trabecular Metal Reconstruction System may also be used with bone graft.

<b>Device Technological Characteristics &amp; Comparison to Predicate Device:</b>	A comparison of device technological characteristics and properties demonstrates that the device is substantial equivalent to the cited predicate devices.
<b>Performance Data:</b>	The <i>Hedrocel Trabecular Metal Reconstructive System</i> was tested per FDA guidance documents and applicable standards for K010378, as referenced in the predicate 023882. In addition, mechanical test data found in MAF #920 indicate the Hedrocel porous tantalum possesses sufficient strength for the indicated use. These results indicate that the subject device will perform as indicated for use in support of weakened bony structures.
<b>Conclusion:</b>	The <i>Hedrocel Trabecular Metal Reconstructive System</i> is substantially equivalent to the cited predicate devices identified in this premarket notification.

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

**AUG 21 2003****Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850**

Ms. Marci Halevi  
Manager of Regulatory Affairs  
Implex Corporation  
80 Commerce Drive  
Allendale, New Jersey 07401-1600

Re: K032282

Trade/Device Name: The Hydrocel Trabecular Metal Reconstruction System  
Regulation Number: 21 CFR 878.3300  
Regulation Name: Surgical mesh  
Regulatory Class: II  
Product Code: EZX  
Dated: July 23, 2003  
Received: July 24, 2003

Dear Ms. Halevi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

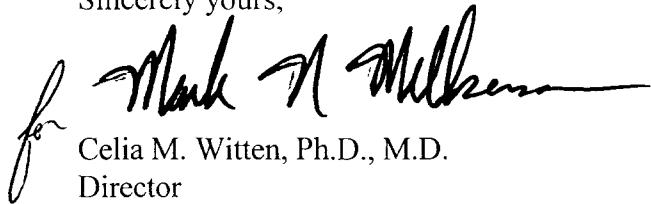
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark M. Witten". To the left of the signature, there is a small, stylized mark that looks like a lowercase 'f' with a diagonal line through it.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and  
Radiological Health

Enclosure

510 (k) Number (if known) :

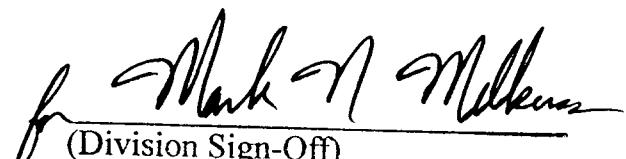
KO 32282

Device Name:

The Hdrocel Trabecular Metal Reconstruction System

Indications For Use:

The Hdrocel Trabecular Metal Reconstruction System is indicated for use in reinforcing weak and/or deficient bony tissues in orthopaedic surgical procedures such as pelvic reconstruction, acetabular reconstruction, cement restriction, and in long bone procedures such as femoral and humeral reconstruction. When used in long bone procedures, ancillary fixation, such as plates and screws, must be used. The Hdrocel Trabecular Metal Reconstruction System may also be used with bone graft.

  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices510(k) Number KO 32282

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Concurrence of CDRH; Office of Device Evaluation (ODE)

Prescripti  
on Use  
(Per 21 CFR 801.109)

OR . . .

Over-The-  
Counter Use

(Optional Format 1-2-95)